

JUN 22 2006

K061157

510(k) PREMARKET NOTIFICATION

BAUSCH & LOMB® SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens

1. Submitter Information:

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14603

Contact Person: Debra Ketchum
Manager, Regulatory Affairs
Telephone No.: (585) 338-8638

2. Device Name:

Classification Name: Soft (hydrophilic) contact lens

Proprietary Name: SofLens® daily disposable (hilafilcon B) Visibility Tinted
Contact Lens

3. Predicate Devices:

SofLens® one day disposable (hilafilcon A) Visibility Tinted Contact Lens
(K974780 and K011718)

SofLens®59 (hilafilcon B) Visibility Tinted Contact Lens (K994125)

510(k) PREMARKET NOTIFICATION

BAUSCH & LOMB® SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens

4. DESCRIPTION OF DEVICE

The SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is a hemispherical flexible shell which covers the cornea and may cover a portion of the adjacent sclera. It consists of a copolymer of 2-hydroxyethyl methacrylate and N-vinyl pyrrolidone, and is 59% water by weight when immersed in a sterile saline solution. This lens is tinted blue with Reactive Blue Dye 246 ((1,4-Bis[4-(2-methacryloxyethyl) phenylamino] anthraquinone). The color additive conforms with 21 CFR Part 73.3106. The lens may also be supplied clear (no tint).

The physical / optical properties of the lens are:

Specific Gravity:	1.119
Refractive Index:	1.4036
Light Transmittance:	C.I.E. Y value - at least 97%
Water Content:	59%
Oxygen Permeability (Dk):	$22 \times 10^{-11} [\text{cm}^3 \text{O}_2 (\text{STP}) \times \text{cm}] / (\text{sec} \times \text{cm}^2 \times \text{mmHg}) @ 35^\circ \text{C}$ (Polarographic Method)

The SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is a hemispherical shell of the following dimensions:

- Diameter: 13.5mm to 15.0mm
- Center Thickness: 0.05mm to 0.75mm
- Base Curve: 7.8mm to 9.5mm
- Powers (Spherical): +20.00D to -20.00D

Each SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is supplied in a plastic blister container with a saline solution. The container is marked with the manufacturing lot number of the lens, the diameter, sphere power, base curve and expiration date.

5. INDICATIONS FOR USE

The SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is indicated for the daily wear correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, that exhibit refractive astigmatism up to 2.00 diopters, that does not interfere with visual acuity. The lens may be prescribed in spherical powers ranging from +20.00D to -20.00D.

The lens is to be prescribed for single-use disposable wear and is to be discarded after each removal.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

A series of preclinical and clinical studies have been completed and were previously submitted under submissions K994125 and K974780.

Non-Clinical Laboratory Testing:

A series of *in vitro* and *in vivo* preclinical toxicology and biocompatibility testing was performed to assess the safety and effectiveness of the contact lens. Testing was performed in accordance with FDA guideline titled *Premarket Notification (510(k)) Guidance Document for Daily Wear Contact Lenses*, May 1994. The non-clinical testing can be found in the currently marketed SofLens®59 (hilafilcon B) Visibility Tinted Contact Lens 510(k) Premarket Notification K994125 cleared on March 3, 2000.

Stability testing has demonstrated a five year expiration date for the sterile lenses.

Clinical Testing:

There is no change in the lens material, the manufacturing process, nor the parameters and properties, therefore, the clinical data previously submitted in K994125 and K974780 supports the clinical safety and effectiveness of the subject device.

Substantial Equivalence

The SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is similar to the SofLens one day disposable (hilafilcon A) and SofLens®59 (hilafilcon B) Visibility Tinted Contact Lenses in that all three lenses fall into FDA Group II for soft (hydrophilic) contact lenses because the ionic content is less than 1% (nonionic polymer material), and the water content is greater than 50% (59% and 70% water) and are manufactured with the same manufacturing process (cast molding). The SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens is different from the SofLens® one day disposable (hilafilcon A) Visibility Tinted Contact Lens in that the lens material has a different USAN name suffix (hilafilcon A vs. hilafilcon B).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2006

Bausch & Lomb, Inc.
c/o Ms. Debra Ketchum
Manager, Regulatory Affairs
1400 N. Goodman Street
Rochester, NY 14609

Re: K061157

Trade/Device Name: Bausch & Lomb SofLens® Daily Disposable (hilafilcon B)
Visibility Tinted Contact Lens

Regulation Number: 21 CFR 886.5925

Regulation Name: Soft (hydrophilic) contact lens

Regulatory Class: Class II

Product Code: MVN

Dated: June 8, 2006

Received: June 9, 2006

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, M.D.", written in a cursive style.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

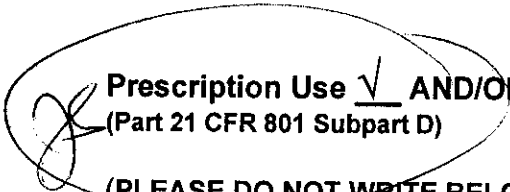
510(k) Number (if known): K061157

Device Name: SofLens® daily disposable (hilafilcon B) Visibility Tinted Contact Lens

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The lens is to be prescribed for single-use disposable wear, and is to be discarded after each removal.

 Prescription Use ☒ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K061157